HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 307 Experimental Treatments for Terminal Conditions
SPONSOR(S): Gaetz; Edwards and others
TIED BILLS: None **IDEN./SIM. BILLS:** SB 460

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice Subcommittee		White	White
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Under the Florida Comprehensive Drug Abuse Prevention and Control Act, cannabis is a Schedule I controlled substance and, as such, criminal penalties ranging from first degree misdemeanors to second degree felonies apply to the unlawful possession, use, sale, purchase, manufacture, delivery, transport, or trafficking of cannabis. Currently, the only statutorily-allowed use of cannabis in this state is set forth in the Compassionate Medical Cannabis Act of 2014 (CCMA), which authorizes dispensing organizations (DOs) approved by the Department of Health to manufacture, possess, sell, and dispense low-THC cannabis for medical use by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

In 2015, the Legislature adopted the Right to Try Act (RTTA). The RTTA authorizes an eligible patient with a "terminal condition," meaning that the patient will die within one year if the condition runs its normal course, to receive an "investigational drug, biological product, or device," meaning a drug, product, or device that has successfully completed phase 1 of a clinical trial, but that has not been approved for general use by the United States Food and Drug Administration.

The bill amends the definition of "investigational drug, biological product, or device" set forth in the RTTA to include cannabis that is manufactured and sold by a DO licensed under the CCMA. The bill further specifies that, notwithstanding the state's laws criminalizing the non-medical use of cannabis, eligible patients under the RTTA or their legal representatives may purchase and possess cannabis for the patient's medical use and DOs may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of cannabis.

The bill does not appear to have a fiscal impact on state or local governments.

The bill takes effect July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Florida's Cannabis Laws

Non-Medical Use of Cannabis

Florida's drug control laws are set forth in ch. 893, F.S., entitled the Florida Comprehensive Drug Abuse Prevention and Control Act (Drug Control Act).[1] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[2] Cannabis is currently a Schedule I controlled substance,[3] which means it has a high potential for abuse, it has no currently accepted medical use in treatment in the United States, and its use under medical supervision does not meet accepted safety standards.[4] Cannabis is defined as:

> All parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not include "low-THC cannabis," as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.[5]

The Drug Control Act contains a variety of provisions criminalizing behavior related to cannabis:

- Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies.[6]
- Section 893.135(1)(a), F.S., makes it a first degree felony[7] to traffic in cannabis, i.e., to possess, sell, purchase, manufacture, deliver, or import more than 25 pounds of cannabis or 300 or more cannabis plants. Depending on the amount of cannabis or cannabis plants trafficked, mandatory minimum sentences of three to 15 years and fines of $25,000 to $200,000 apply to a conviction.[8]
- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[9] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[10]

Florida's Medical Necessity Defense

Florida courts have held that persons charged with offenses based on the possession, use, or manufacture of marijuana may use the medical necessity defense, which requires a defendant to prove that:

- He or she did not intentionally bring about the circumstance which precipitated the unlawful act;
- He or she could not accomplish the same objective using a less offensive alternative; and
- The evil sought to be avoided was more heinous than the unlawful act.[11]

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[1] s. 893.01, F.S.
[2] s. 893.03, F.S.
[3] s. 893.03(1)(c)7., F.S.
[4] s. 893.03(1), F.S.
[5] s. 893.02(3), F.S.
[6] A first degree misdemeanor is punishable by up to one year in county jail and a $1,000 fine; a third degree felony is punishable by up to five years imprisonment and a $5,000 fine; and a second degree felony is punishable by up to 15 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.
[7] A first degree felony is punishable by up to 30 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.
[8] s. 893.13(1)(a), F.S.
[9] Drug paraphernalia is defined in s. 893.145, F.S., as:
> All equipment, products, and materials of any kind which are used, intended for use, or designed for use in the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.

[10] s. 893.147, F.S.

In *Jenks v. State,*[12] the defendants, a married couple, suffered from uncontrollable nausea due to AIDS treatment and had testimony from their physician that they could find no effective alternative treatment. The defendants tried cannabis, and after finding that it successfully treated their symptoms, decided to grow two cannabis plants.[13] They were subsequently charged with manufacturing and possession of drug paraphernalia. Under these facts, the First District Court of Appeal found that "section 893.03 does not preclude the defense of medical necessity" and that the Jenks met the criteria for the medical necessity defense.[14] The court ordered the Jenks to be acquitted.[15]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.[16] More recently, the State Attorney's Office in the Twelfth Judicial Circuit cited the medical necessity defense as the rationale for not prosecuting a person arrested for cultivating a small amount of cannabis in his home for his wife's medical use.[17]

Compassionate Medical Cannabis Act of 2014

The Compassionate Medical Cannabis Act of 2014[18] (CMCA) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[19] for the medical use[20] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

The CMCA provides that a Florida licensed allopathic or osteopathic physician who has completed certain training[21] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat the disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for the patient. To meet the requirements of the CMCA, each of the following conditions must be satisfied:

- The patient must be a permanent resident of Florida.
- The physician must determine that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient.[22]
- The physician must register as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the Department of Health (DOH) and must update the registry to reflect the contents of the order.

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[11] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla.1991).
[12] 582 So.2d 676 (Fla. 1st DCA 1991).
[13] *Id*.
[14] *Id*.
[15] *Id*.
[16] 739 So.2d 333 (Fla. 1st DCA 1998).
[17] *Interdepartmental Memorandum*, State Attorney's Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013 (on file with Judiciary Committee staff).
[18] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.
[19] The act defined "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S. Eleven states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol): Alabama, Florida, Iowa, Kentucky, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Utah, and Wisconsin. Twenty-three states, the District of Columbia, and Guam have laws that permit the use of marijuana for medicinal purposes. See infra note 28. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (Tables 1 and 2), (last visited on March 27, 2015).
[20] Section 381.986(1)(c), F.S., defines "medical use" as "administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient." Section 381.986(1)(e), F.S., defines "smoking" as "burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer."
[21] Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing
[22] If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record. s. 381.986(2)(b), F.S.

- The physician must maintain a patient treatment plan and must submit the plan quarterly to the University of Florida College Of Pharmacy.
- The physician must obtain the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis.[23]

Under the CMCA, DOH was required to approve five dispensing organizations (DOs) by January 1, 2015, with one DO in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.[24] To be approved as a DO, an applicant must establish that it:

- Possesses a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- Is operated by a nurseryman;
- Has been operating as a registered nursery in this state for at least 30 continuous years;
- Has the technical and technological ability to cultivate and produce low-THC cannabis;
- Employs a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis; and
- Other specified requirements.[25]

Implementation by DOH of the DO approval process was delayed due to litigation that challenged proposed rules addressing the initial application requirements for DOs, revocation of DO approval, and inspection and cultivation authorization procedures for DOs. Such litigation was resolved on May 27, 2015, with an order entered by the Division of Administrative Hearings holding that the challenged rules do not constitute an invalid exercise of delegated legislative authority.[26] Thereafter, the rules took effect on June 17, 2015.[27]

The application process to become a DO closed on July 8, 2015, with 28 applications received by the DOH. As of November 13, 2015, the DOH is continuing to conduct its review process to select the five approved DOs as directed by statute.[28]

The CMCA provides that it is a first degree misdemeanor for:

- A physician to order low-THC cannabis for a patient without a reasonable belief that the patient is suffering from a required condition; or
- Any person to fraudulently represent that he or she has a required condition to a physician for the purpose of being ordered low-THC cannabis.[29]

The CMCA specifies that notwithstanding ss. 893.13, 893.135, or 893.147, F.S., or any other law that:

- Qualified patients[30] and their legal representatives may purchase and possess low-THC cannabis up to the amount ordered for the patient's medical use.
- Approved dispensing organizations (DOs) and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis. Such DOs and their owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., relating to pharmacies.[31]

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[23] s. 381.986(2), F.S.
[24] s. 381.986(5)(b), F.S.
[25] *Id.*
[26] *Baywood v.Nurseries Co., Inc. v. Department of Health*, Case No. 15-1694RP (Fla. DOAH May 27, 2015).
[27] Rule Chapter 64-4, F.A.C.
[28] Telephone call with staff of the Department of Health (November 13, 2015).
[29] s. 381.986(3), F.S.
[30] Section 381.986(1)(d), F.S., provides that a "qualified patient" is a Florida resident who has been added by a physician licensed under ch. 458, F.S. or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a dispensing organization.
[31] s. 381.986(7), F.S.

Interaction of State Medical Marijuana Laws with Federal Law

The Federal Controlled Substances Act[32] lists cannabis as a Schedule 1 drug with no accepted medical uses.[33] Like the Florida's Drug Control Act, the Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, etc. cannabis.[34] A first misdemeanor offense for possession of cannabis in any amount can result in a $1,000 fine and up to year in prison, climbing for subsequent offenses to as much as $5,000 and three years.[35] Selling and cultivating cannabis are subject to even greater penalties.[36]

Although state medical cannabis laws protect patients from prosecution for the legitimate use of cannabis under the guidelines established in that state, such laws do not protect individuals from prosecution under federal law should the federal government choose to enforce those laws. in recent years, however, the federal government appears to have softened its stance on cannabis.

In August of 2013, the United States Justice Department (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century." [37] This document details the federal government's changing stance on low-level drug crimes announcing a "change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins."[38]

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that appeared to relax the federal government's cannabis-related offense enforcement policies.[39] The memo stated that the USDOJ was committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational ways, and outlined eight areas of enforcement priorities.[40] These enforcement priorities focused on offenses that would result in cannabis being distributed to minors, cannabis sale revenues going to criminal gangs or other similar organizations, and cannabis being grown on public lands.[41] The memo indicated that outside of the listed enforcement priorities, the federal government would not enforce federal cannabis-related laws in states that have legalized the drug and that have a robust regulatory scheme in place.[42]

Right to Try Act

During the 2015 Regular Session, the Legislature enacted the "Right to Try Act" (RTTA), which authorizes a manufacturer to provide an eligible patient with an investigational drug, biological product, or device that has successfully completed phase 1 of a clinical trial, but that has not been approved for general use by the United States Food and Drug Administration (FDA), and that remains under investigation in a clinical trial approved by the FDA.[43] The RTTA allows manufacturers to contract with and dispense investigational drugs directly to patients without licensure or regulation under chapter 465, F.S., by the Board of Pharmacy.[44]

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[32] 21 U.S.C. ss. 801-971.
[33] 21 U.S.C. s. 812.
[34] 21 U.S.C. ss. 841-65.
[35] 21 U.S.C. s. 844.
[36] 21 U.S.C. ss. 841-65.
[37] USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century*, http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on Nov. 15, 2015).
[38] *Id*.
[39] *See* USDOJ memo on "Guidance Regarding Marijuana Enforcement," August 29, 2014, http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on Nov. 15, 2015).
[40] *Id*.
[41] *Id*.
[42] *Id*.
[43] s. 499.0295(1)-(3), F.S.
[44] s. 499.0295(3) and (7), F.S.

To be eligible to access such drugs, products, or devices, a patient must have a "terminal condition" which is defined as "a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course."[45] The eligible patient's treating physician must attest to the terminal condition, such condition must be confirmed by a second evaluation by a board-certified physician in an appropriate specialty, and the patient must have considered all other approved treatments.[46]

The RTTA also requires the patient, a parent of a minor patient, a court-appointed guardian for the patient, or a health care surrogate designated by the patient to provide written informed consent prior to accessing an investigational drug, biological product, or device. The written informed consent must include:

- An explanation of the currently approved products and treatments for the patient's terminal condition.
- An attestation that the patient agrees with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.
- Identification of the specific name of the investigational drug, biological product, or device.
- A realistic description of the most likely outcome, detailing the possibility of unanticipated or worse symptoms.
- A statement that death could be hastened by use of the investigational drug, biologic product, or device.
- A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for treatment consequent to the use of the investigational drug, biological product, or device, unless required to do so by law.
- A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment, and that hospice care may be reinstated if treatment ends and the patient meets hospice eligibility requirements.
- A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless negotiated otherwise.[47]

The RTTA specifies that there is no obligation on the part of any manufacturer to provide a requested investigational drug, biologic product, or device, but that a manufacturer may do so with or without compensation.[48] The eligible patient may be required to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.[49] The RTTA allows, but does not require, a health plan, third-party administrator, or governmental agency to cover the cost of an investigational drug, biological product, or device.[50] The RTTA exempts a patient's heirs from any outstanding debt associated with the patient's use of the investigational drug, biological product, or device.[51]

The RTTA prohibits the Board of Medicine or Board of Osteopathic Medicine from revoking, suspending, or denying renewal of a physician's license based solely on the physician's recommendation to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. It also prohibits action against a physician's Medicare certification for the same reason.[52]

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[45] s. 499.0295(2)(c), F.S.
[46] s. 499.0295(2)(a), F.S.
[47] s. 499.0295(2)(d), F.S.
[48] s. 499.0295(3), F.S.
[49] *Id.*
[50] s. 499.0295(4) and (9), F.S.
[51] s. 499.0295(6), F.S.
[52] s. 499.0295(7), F.S.

The RTTA provides liability protection for a manufacturer, person, or entity involved in the use of an investigational drug, biological product, or device in good faith compliance with the provisions of the bill and exercising reasonable care.[53]

Effect of Bill

The bill amends the definition of "investigational drug, biological product, or device" set forth in the RTTA to include cannabis that is manufactured and sold by a DO licensed under the CCMA. The bill further specifies that, notwithstanding the state's laws criminalizing the non-medical use of cannabis:

- Eligible patients under the RTTA or their legal representatives may purchase and possess cannabis for the patient's medical use.
- DOs and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of cannabis and are not subject to licensing and regulation by the Board of Pharmacy under ch. 465, F.S.

The bill also specifies that the RTTA does not impair the license of an approved DO under the CCMA.

The bill specifies that the terms "manufacture,"[54] "possession,"[55] "deliver,"[56] "distribute,"[57] and "dispense"[58] are defined as provided in s. 893.02, F.S.

B. SECTION DIRECTORY:

Section 1. Amends s. 499.0295, F.S., relating to experimental treatments for terminal conditions.

Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill does not appear to have any impact on state government revenues.

2. Expenditures:

[53] s. 499.0295(8), F.S.

[54] Section 893.02(15)(a), F.S., provides that "manufacture" means "the production, preparation, propagation, compounding, cultivating, growing, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance by: 1. A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice. 2. A practitioner, or by his or her authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis, and not for sale."

[55] Section 893.02(19), F.S., provides that "possession" includes "temporary possession for the purpose of verification or testing, irrespective of dominion or control."

[56] Section 893.02(6), F.S., provides that "deliver" or "delivery" means "the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship."

[57] Section 893.02(8), F.S., provides that "distribute" means "to deliver, other than by administering or dispensing, a controlled substance."

[58] Section 893.02(7), F.S., provides that "dispense" means "the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user."

The bill does not appear to have any impact on state government expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not appear to have any impact on local government revenues.

2. Expenditures:

The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

B. RULE-MAKING AUTHORITY:

The bill does not appear to create the need for rulemaking or rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill refers to the licensure of DOs under the CMCA; however, the CMCA refers to the "approval," rather than "licensure," of DOs by the DOH.

The bill authorizes eligible patients to purchase "cannabis" from a DO licensed under the CMCA. Such DOs, however, are only authorized to manufacture, possess, sell, and dispense "low-THC cannabis." If the intent of the bill is to only authorize "low-thc cannabis" for "eligible patients" under the RTTA, the bill should be amended to use the term "low-thc cannabis." If the intent is to permit DOs to manufacture, possess, sell, and dispense any type of cannabis, it may be desirable for the bill to also amend provisions in the CMCA to ensure that DOs have the technical and technological ability to produce all forms of cannabis and that DOH is authorized to regulate such production and distribution by DOs.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

N/A